UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/573,014	08/09/2006	Abraham Martinus Cohen Stuart	60838.000600	2587

21967 7590 09/02/2009

HUNTON & WILLIAMS LLP
INTELLECTUAL PROPERTY DEPARTMENT
1900 K STREET, N.W.
SUITE 1200
WASHINGTON, DC 20006-1109

EXAMINER	
KASSA, TIGABU	
ART UNIT	PAPER NUMBER
1619	

MAIL DATE	DELIVERY MODE
09/02/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/573,014	COHEN STUART ET AL.	
	Examiner	Art Unit	
	TIGABU KASSA	1619	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 June 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-59* is/are pending in the application.

4a) Of the above claim(s) *54-59* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *35-53* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 35-53 are under consideration in the instant office action. Claims 54-59 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claims. Claims 1-34 are cancelled.

Election/Restrictions

Applicant's election with traverse of Group I (claims 35-53) in the reply filed on 06/26/09 is acknowledged. The traversal is on the ground(s) that the search and examination of the two groups does not present an undue burden to the examiner. This is not found persuasive because as the examiner showed the inventions I and II lack the same special technical feature. The polymeric micelle of the instantly claimed invention is disclosed by Sakurai et al. in EP 0721776 B1.

The requirement is still deemed proper and is therefore made FINAL.

Priority

Acknowledgment is made of applicant's claim for foreign priority based on an application filed in European patent office on 09/25/03. It is noted, however, that applicant has not filed a certified copy of the EP 03078031.6 application as required by 35 U.S.C. 119(b).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 35-53 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Note: The dependant claims are included in the rejection solely because they depend on indefinite independent claims.

Claim 36 states "the process according to claim" but fails to indicate the claim from which it depends.

Claims 35 and 48 do not clearly indicate whether the surface being coated by the micelle is interior to or exterior to the micelle.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 35-53 are rejected under 35 U.S.C. § 102(b) as being anticipated by Sakurai et al. (EP 0721776).

Applicants claim a process for the modification of or treatment of a surface comprising coating a surface with at least one polymeric micelle as specified. Instant claim 36-37 recite intended uses. Instant claim 38 recites the process according to claim 35, wherein the polymeric micelle comprises at least a first and a second polymer. Instant claim 39 recites the process according to claim 38, wherein the first polymer and the second polymer are oppositely charged. Instant claim 40 recites the process according to claim 39, wherein the first polymer is a block

polymer with an ionic block comprising at least 6 chargeable groups. Instant claim 41 recites the process according to claim 40, wherein the ionic block is selected from the group consisting of polyacrylic acid, polymethacrylic acid, poly-(dimethylamino ethylmethacrylate) and poly(N-alkyl-4-vinylpyridinium). Instant claim 42 recites the process according to claim 38, wherein the first polymer comprises at least a hydrophilic and neutral block. Instant claim 43 recites the process according to claim 42, wherein the hydrophilic and neutral block is a polyethylene glycol or a polyacrylamide, or a combination thereof. Instant claim 44 recites the process according to claim 38, wherein the second polymer is a homopolymer, a random copolymer, a block polymer, a natural polymer, or a derivative thereof. Instant claim 45 recites the process according to claim 44, wherein the homopolymer is selected from the group of polyacrylic acid, polymethacrylic acid, poly-(dimethylamino ethylmethacrylate) and poly(N-alkyl-4-vinylpyridinium). Instant claims 46-47 recite intended uses.

Sakurai et al. disclose a block copolymer of polyethylene glycol (non-chargeable segment) and polyamino acid (chargeable segment), which is capable of providing an electrostatic bonding type macromolecular micelle drug carrier (paragraph 0008). Sakurai et al. discloses that the non-chargeable segments can be polyethylene glycol, polypropylene glycol, polysaccharide, polyacrylamide etc (paragraph 0014). The chargeable segments could be polyaspartic acid, polylysine, polyarylic acid, polymethacrylic acid, etc (paragraph 0015). The micelles physically adsorb the drug (paragraph 0005), which indicates that the drug surfaces are inherently coated with the micelles. Sakurai et al. disclose an illustrative example wherein a chicken albumin lysozyme was dissolved in distilled water and polyethylene glycol-polyasparatic acid block copolymer is dissolved in distilled water are mixed resulting in a

micelle adsorbing the lysozyme via electrostatic bonding (see example 3). These teachings clearly anticipate instant claims 35-47. With regard to instant claims 36-37 and 46-47 the limitations are intended use, therefore, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is the same and is capable of performing the recited intended uses the prior art reference clearly anticipates the limitations.

Applicant claims a process for modifying a surface or treating a surface, said process comprising the steps of: (i) mixing at least a first and a second polymer in such amounts that the resulting mixture has a fraction of the total number of cationic polymeric groups over the total number of charged groups in the range of 0.2 to 0.8, wherein the first and the second polymer are oppositely charged and wherein the first polymer is a block polymer comprising at least a hydrophilic and neutral block; and (ii) bringing the resulting mixture under aqueous conditions in contact with the surface, wherein the salt concentration in both steps is less than 1 M. Instant claim 49 recites the process according to claim 48, wherein the first polymer is a block polymer with an ionic block comprising at least 6 chargeable groups. Instant claim 50 recites the process according to claim 49, wherein the ionic block is selected from the group consisting of polyacrylic acid, polymethacrylic acid, poly-(dimethylamino ethylmethacrylate) and poly(N-alkyl-4-vinylpyridinium). Instant claim 51 recites the process according to claim 50, wherein the hydrophilic and neutral block is a polyethylene glycol, polyglycerylmethacrylate or a polyacrylamide, or a combination thereof. Instant claim 52 recites the process according to claim 48, wherein the second polymer is a homopolymer, a random copolymer, a block polymer, a

natural polymer, or a derivative thereof. Instant claim 53 recites the process according to claim 52, wherein the homopolymer is selected from the group of polyacrylic acid, polymethacrylic acid, poly-(dimethylamino ethylmethacrylate) and poly(N-alkyl-4-vinylpyridinium).

Sakurai et al. also disclose an illustrative example wherein a polymeric micelle is prepared from poly-L-lysine and polyethylene glycol-polyasparatic acid block copolymer. Based on the examiner's calculation polylysine which is positively charged contains (20*0.43= 8.6 residues) and the polyasparatic acid which is negatively charged (20*1= 20 residues). The total number of charged groups is 28.6. The examiner calculates the fraction of the cationic groups to the total number of charged groups 8.6/28.6=0.30 (see example 1). Sakurai et al. also disclose that the carriers disclosed in the examples are capable of stably carrying a drug under the effect of polymeric micelles (paragraph 0045). As described above Sakurai et al. disclose that the non-chargeable segments can be polyethylene glycol, polypropylene glycol, polysaccharide, polyacrylamide etc (paragraph 0014). The chargeable segments could be polyaspartic acid, polylysine, polyarylic acid, polymethacrylic acid etc (paragraph 0015). The micelles physically adsorb the drug (paragraph 0005), which indicates that the drug surfaces are inherently coated with the micelles. These teachings clearly anticipate instant claims 48-53.

Conclusion

Claims 35-53 are rejected. Claims 54-59 are withdrawn. Claims 1-34 are cancelled. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TIGABU KASSA whose telephone number is (571)270-5867. The examiner can normally be reached on 9 am-5 pm Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Tigabu Kassa 08/27/09

/Mina Haghighatian/

Primary Examiner, Art Unit 1616